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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,559	06/18/2001	Michael Kramer	113.1010	3025

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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/787,559	KRAMER ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,8-10,17,24 and 29-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,10,17,24 and 29-31* is/are rejected.

7)☒ Claim(s) *8 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 2/7/2007.

The amendment filed 2/7/2007 is acknowledged and has been entered.

Claims 2, 3, 8-10, 17, 24, 29-31 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 10, 17, 29, 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or

chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Here, the claims are drawn to a genus of isolated nucleic acid molecules which encode proteins that are functionally identical to a protein that occurs naturally in human keratinocytes and is increasingly expressed when keratinocytes are in an activated state compared to non-activated keratinocytes, wherein the nucleic acid molecules have a sequence of SEQ ID NO:1, SEQ ID NO:4 or the antisense strands of SEQ ID NO:1 or SEQ ID NO:4. The phrase "wherein the nucleic acid molecules have a sequence of SEQ ID NO:1..." does not explicitly limit the nucleic acid molecules to the nucleic that comprise the sequences of the SEQ ID Nos. Rather, given the broadest reasonable interpretation, the claims encompass any nucleic acid sequence that comprises any partial sequence of SEQ ID NO: 1, SEQ ID NO: 4, or the antisense strands of SEQ ID Nos: 1 or 4, wherein the nucleotide sequence encodes a protein that is functionally equivalent to any protein that occurs naturally in human keratinocytes and is increasingly expressed when keratinocytes are in an activated state compared to non-activated keratinocytes. It is noted that the claims do not recite any particular biological function of the encoded protein, only that it is functionally equivalent to another protein. Furthermore, the claims do not recite any particular elements that must be conserved among the members of the genus. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry,

whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). In this case, the skilled artisan cannot envision the detailed chemical structure of the genus of nucleic acid molecules encompassed by the claims; therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only isolated nucleic acids sequences which encode the amino acid sequence set forth in SEQ ID NO: 2 or SEQ ID NO: 3 (identified as pKe#122), such as SEQ ID NO: 1 and SEQ ID NO: 4 meet the written description provision of 35 U.S.C. §112, first paragraph and limiting the claims as such would obviate this rejection. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 24, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Mierendorf et al. (U.S. patent 5,629,179, previously of record).

It is noted that claim 24 is drawn to a reagent for the indirect detection of a protein that occurs in human keratinocytes, said protein being increasingly expressed in activated keratinocytes as compared to non-activated keratinocytes, wherein the reagent encompasses at least one nucleic acid, which hybridizes with the nucleotide sequence of SEQ ID NO: 1, SEQ ID NO: 4, the antisense strand of SE0 ID NO: 1, or the antisense strand of SEQ ID NO: 4. As such, the claims encompass any nucleic acid sequence which hybridizes with SEQ ID NO: 1, SEQ ID NO: 4, the antisense strand of SE0 ID NO: 1, or the antisense strand of SEQ ID NO: 4.

Mierendorf et al. teaches a method and kit for making a cDNA library wherein the kit comprises random octamer oligonucleotides (i.e. nucleic acids that are 8 nucleotides in length) over every possible sequence (see column 7, line 59-column 8, line 6). Mierendorf et al. teaches a kit comprising every possible octamer oligonucleotide. Therefore, the kit taught by Mierendorf et al. includes 8mer (i.e. octamer) oligonucleotides which are complementary to parts of SEQ ID No. 1 and SEQ ID No. 4 and which would hybridize to SEQ ID NO: 1 and SEQ ID NO: 4. Furthermore, claim 31 merely indicates that the protein which is indirectly detected by the reagent is pKe#122. Since SEQ ID NO: 1 and 4 encode pKe#122, claim 31 still encompasses the oligonucleotides of Mierendorf indicated above.

It is noted that amending the claims to be limited in scope to the nucleotide sequences that are SEQ ID NO: 1 and SEQ ID NO: 4 would obviate this rejection.

Claim Objections

Claims 8 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 11/2/2006 have been fully considered and, in view of the amendment to the claims, are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration a new ground(s) of rejection is made in view of the amendment to the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.